K092876

SECTION 7 – 510(K) SUMMARY

OCT 16 2009

Applicant Information

Submitter's Name and Address:

St. Jude Medical
177 County Road B, East
St. Paul, MN 55117

Contact Name

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Submission Prepared

September 15, 2009

Device Information

Proprietary Name:

SJM Attune Flexible Adjustable Annuloplasty Ring

Common or Usual Name:

Flexible Adjustable annuloplasty ring
Mitral/Tricuspid repair ring

Classification:

Class II per 21 CFR 870.3800,
Annuloplasty rings

Predicate Device:

SJM Attune Ring model AFR-(size)

510(k) No. K083835 – cleared January 23, 2009

Device Description:

The SJM Attune Flexible Adjustable Annuloplasty Ring is a fully flexible ring fabricated from a medical grade silicone core surrounded by a polyester sewing cuff and containing a suture that will allow for adjustment after implantation.

Intended Use:

The SJM Attune Flexible Adjustable Annuloplasty Ring is intended for mitral or tricuspid heart valve repair using conventional open heart, minimally invasive or robotic surgical techniques.

Comparison of Required Technological Characteristics

SJM considers the SJM Attune Annuloplasty ring to be substantially equivalent in technological characteristics (e.g. design and materials) and intended use to the predicate device. The table below is a comparison of the equivalency characteristics between the SJM Attune Annuloplasty Ring and the predicate device.

Item	Equivalency
Principles of Operation	Identical
Product Labeling	Substantially Equivalent
Indications for Use	Identical
Physical Characteristics	Substantially Equivalent
Anatomical Sites	Identical
Target Population	Identical
Performance Testing	Substantially Equivalent
Safety Characteristics	Substantially Equivalent
Packaging	Identical
Sterilization	Identical
Shelf-Life	Identical

Summary of Non-Clinical Tests

The following performance characteristics were evaluated:

- Ring Tensile Strength
- Suture Pullout Test
- Adjustment Suture Testing
- MR Safety Evaluation
- Biological Evaluation
- Sterilization Parameter Evaluation

Conclusion

The additional sizes of the SJM Attune Ring are, with respect to intended use and technological characteristics, substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

St. Jude Medical
c/o Mr. Thomas Rademacher
Regulatory Affairs Specialist
177 County Road B, East
St. Paul, MN 55117

OCT 16 2009

Re: K092876
SJM Attune Flexible Adjustable Annuloplasty Ring Model AFR
Regulation Number: 21 CFR 870.3800
Regulation Name: Annuloplasty ring
Regulatory Class: Class II (two)
Product Code: KRH
Dated: September 15, 2009
Received: September 18, 2009

Dear Mr. Rademacher:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 2

Indications for Use Statement

Indications for Use

510(k) Number (if known): K092876
Device Name: SJM™ Attune Flexible Adjustable Annuloplasty Ring
Indications For Use:

The SJM™ Attune Annuloplasty Ring is indicated for use in the repair of a mitral or tricuspid valve that is diseased or damaged due to acquired or congenital valvular disease.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092876